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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,263	10/10/2000	Noah Syroid	3040.2	5909

56273 7590 12/17/2008

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EXAMINER	
SIMS, JASON M	
ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
12/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/686,263	SYROID ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 3/19/2008, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 3/19/2008, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 6-49 are the current claims hereby under examination.

The following is a newly applied rejection, which has been necessitated by amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-13, 15-24, 41-43 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 and all claims dependent therefrom comprise the newly amended claim wording further limiting a drug display monitor. However, support for such a display to comprise an algorithm has not been found in the instant specification. A display is not defined as being capable of comprising an algorithm as now claimed. The display

monitor is only capable of displaying data, but not processing data, such as mathematically determine a present and future probability of effectiveness as claimed. Therefore, the amended claim wording has been deemed new matter.

Claim Rejections - 35 USC § 102

Response to Arguments

Applicant's arguments, filed 3/19/2008, with respect to the rejection of claims under 35 USC 102 have been fully considered and are persuasive because of applicant's arguments and amendments to the claims. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 103

The following rejections are being newly made, which has been necessitated by amendment:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7-10, 12-13, 15-24, 41-43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al (US P/N 5,088,981).

The claims are directed to a system for data representation comprising:

- A drug delivery system;
- A data stream device;
- A drug display monitor in communication with the data stream device, wherein the drug display monitor includes an algorithm configured to mathematically determine a present and future probability of effectiveness of at least one drug introduced into the subject by the drub delivery system, wherein the present and future probabilities of effectiveness include a correlation of a predicted drug effect site concentration based on modeled pharmacokinetic data and a probability of achieving a bodily effect on the patient based on modeled pharacodynamic data, and wherein the drug display monitor is configured to depict, in real time, the present and future probability of effectiveness including predicted pharmacokinetic effect site concentrations depicted as a percent of a concentration value corresponding to a known pharmacodynamic probability of causing a particular bodily effect.

The following excerpt is from M.P.E.P. 2106 Section VI (DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 102 and 103 (particular emphasis on bolded areas) and is applied to the below 35 U.S.C. 103 rejection, wherein “data defining three dimensional structure” of either protease or potential ligand is considered “non-functional descriptive" material, i.e. mere arrangement of data.

The following examples are provided for in the M.P.E.P. regarding situations of non-functional descriptive material.

> As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. **If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be rejected by Office personnel under 35 U.S.C. 102.** Once distinctions are identified between the claimed invention and the prior art, those distinctions must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103. Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See Dann v. Johnston, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976); In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).
>
> If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. In re Dembiczak, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). **Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. In re Ngai, F.3d, 2004 WL 1068957 (Fed. Cir. May 13, 2004).< Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).** Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

> Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is imply a rearrangement of nonfunctional descriptive material.

With regards to amended claim 6 (and all claims dependent therefrom), the wherein limitation involving the display is data that is considered to be non-functional descriptive material as it is not part of a system that it can impart functionality when instructed, i.e. a display, is only capable of displaying, not executing an algorithm to process data as claimed, and is not being given patentable weight. Therefore, a reference capable of displaying similar types of data is being broadly and reasonably interpreted as also being capable of displaying the intended use data as well.

Howson et a1 ('981) discloses a system for data representation comprising a drug delivery system (52, 54) a data stream device (50) in communication with the drug delivery device system (52, 54) and a drug delivery display monitor (28), in communication with a data stream device (50), see figures 1 and 2. Furthermore, Howson et al ('981) discloses that the drug delivery system comprises a simulator, which simulates bolus, infusion and anesthetic drug administration (col. 4 line 3). Moreover, Howson et al ('981) discloses a drug display monitor (28) comprising a data decoder (20) receiving data from the data stream device (50); a dosage calculator (32) receiving decoded data from the data decoder; a drug modeler (26) and normalizer (24) receiving calculated data from the data decoder; a storage device (16), receiving drug and dosage data from the drug modeler and normalizer; and a display generator (28), wherein the display generator produces a display of more than one drug dosages, drug

name, past, present and predicted drug site concentration and effect site concentration in three-dimensional form and a system for data representation comprising a processor (16), computing drug models, producing an internal representation of drug display data and decoding a data stream; a memory unit in communication with the processor; a graphics adapter (24c) in communication with the processor and a display monitor in communication with the graphics adapter, see figures 1 and 2 and col. 13, 14 and 15. Additionally, Howson et al ('981), at col. 7, lines 5-65 discloses how the drug concentrations and dosages are calculated based on information obtained from databases, in real time, that include patient history information, drug database information, and pharmacokinetic algorithms to provide accepted drug dosage ranges, drug to drug interaction, and mathematical support for dose-response information, which represents a monitor that is configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject. Moreover, a monitor that is configured to depict present and future drug dosages, which uses databases and algorithms to aid in calculating a proper drug dosage, is depicting a probability of effectiveness in the form of a drug dosage. The calculated drug dosage for a particular patient is based on that patient's history information, which may include past treatment history in coordination with drug database information and pharmacokinetic algorithms, and the result is a proper drug dosage to be delivered to cause a particular drug concentration in the patient, which has a particular real-time probability of effectiveness based on current and past available data. Howson et al

('981) further discusses at col. 10, lines 55-67 and col. 12, lines 20-66, the design of profiles for patient drug delivery and how these profiles, when complete, have the computer validate the profile to ensure that arithmetic, procedural, or conceptual errors have not been made, and the profile can even be simulated or tested in software prior to the instructions being executed, which reads on the amended phrase "probability of effectiveness." Howson et al ('981), at col. 15 and 16, further discloses a system that can be used to manage each of the infused drugs and other drugs as well and the user can ask the computer to use pharmacokinetic algorithms to help derive optimum profiles for the patient. The system is a comprehensive medication management system, which is configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject.

Howson et al. does not explicity teach a drug display monitor configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject, wherein the present probability of effectiveness includes a correlation of a predicted drug concentration based on modeled pharmacokinetic data and a probability of pharmacodynamic effectiveness based on modeled pharmacodynamic data.

However, the examiner views a computer monitor being capable and already configured to displaying any type of data stream. In particular, Howson et al. does teach a monitor that displays real time drug effectiveness data streams. Therefore, it is

inherent that a computer monitor is configured and capable of displaying data streams as it is the definitive function of the monitor to do so. Upon viewing the claims, the intended use limitations are not given weight because they are only limiting to the data prior to becoming part of the data stream, but the resulting data stream is just that, a data stream, wherein the monitor is inherently configured and capable of displaying said data stream. Moreover, a monitor is capable of displaying data streams, wherein a data stream may be any type of probability and specifically it may be a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject, wherein the present probability of effectiveness includes a correlation of a predicted drug concentration based on modeled pharmacokinetic data and a probability of pharmacodynamic effectiveness based on modeled pharmacodynamic data and therefore be displayed on the monitor taught by Howson et al.

Howson et al ('981) discloses the drug delivery system further comprising an infusion pump (14 see col. 10 line 13) as in claim 7.

Howson et al. teaches a processor already configured to processing drug model data. However, Howson et al. does not explicitly teach a processor configured for such functionality as causing the graphics adapter and the display monitor to graphically depict a percent likelihood that the at least one drug has a desired effect.

However, the examiner views a processor, which is already capable and configured to displaying drug model data will inherently be configured such functionality as causing the graphics adapter and the display monitor to graphically depict a percent

likelihood that the at least one drug has a desired effect. In particular, Howson et al. does teach a processor that inherently causes the graphics adapter to display real time drug effectiveness data streams. Therefore, it is inherent that the processor is configured and capable of performing such functionality as recited in the claims. Upon viewing the claims, the intended limitations are not given weight because they are only limiting to the data prior to becoming part of the data stream, but the resulting data stream is just that, a data stream, wherein the processor is inherently configured and capable of processing said data stream.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al ('981) as applied to claims 6 and 8 above, and further in view of Teeple Jr. U.S. Patent Number 5,925,014.

The claims are drawn to a system for data representation comprising a drug delivery system, a data stream device and a drug display monitor, wherein the drug delivery system comprises an infusion pump, a gas administration machine, and one or more bolus injection apparatus and the simulator simulates anesthetic drugs.

Howson et al ('981) fails to disclose an anesthetic administration machine and one or more bar coded syringes.

Teeple Jr. discloses an anesthetic administration machine (30 see figure 3); and one or more bar coded syringes (31-33 see figure 3).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the drug delivery system of Howson et at ('981) by

incorporating anesthesia administration and bar coded syringes as taught by Teeple Jr. ('014) in order to insure that the proper drug mix is achieved, reducing if not eliminating the possibility for human error (Teeple Jr. col. 4 line 67).

Claims 6-11, 14-16, 19-24, 29-32, 35-38, 41-46, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kern et al. (1997) in view of Minto et al. (1998).

The claims are directed to a system for data representation comprising:

- A drug delivery system;
- A data stream device;
- A drug display monitor in communication with the data stream device, wherein the drug display monitor includes an algorithm configured to mathematically determine a present and future probability of effectiveness of at least one drug introduced into the subject by the drug delivery system, wherein the present and future probabilities of effectiveness include a correlation of a predicted drug effect site concentration based on modeled pharmacokinetic data and a probability of achieving a bodily effect on the patient based on modeled pharmacodynamic data, and wherein the drug display monitor is configured to depict, in real time, the present and future probabilities of effectiveness including predicted pharmacokinetic effect site concentrations depicted as a percent of a

concentration value corresponding to a known pharmacodynmic probability of causing a particular bodily effect.

With regards to limitations of claim 6: Kern et al. teach at the abstract a pharmacokinetic and pharmacodynamic based method for calculating the bolus dose size. Kern et al. at pages 191-192, discuss a drug delivery system and a data stream device that enables the administration of a drug, such as an anesthetic, to a patient wherein the concentration of the drug in the blood can be maintained. Furthermore, Kern et al. at page 192, last paragraph, and page 198, teach a minibolus strategy is developed for a computer-controlled delivery method that uses a pharmacokinetic and pharmacodynamic model to estimate the drug concentration in the biophase and consequently, the theoretical drug effect, which reads on a predicted pharmacokinetic effect site concentrations depicted as a percent of a concentration value corresponding to a known pharmacodynamic probability of causing a particular bodily effect. Kern et al. at page 195 first two paragraphs, teach that peak effect from a dose occurs after the peak concentration in the bloodstream and therefore a frequency response can be used to predict the biophase response to different drug dosing intervals, which reads on calculating present and future probability of effectiveness of a drug introduces into a subject. Kern et al. at page 201, last paragraph teach wherein the model calculates the future probability of effectiveness for a dose. Kern et al. at page 203 and page 204 teach how the simulation achieves a desired level of drug effect and maintains that effect within a range that is clinically acceptable. Kern et al. at page 202 teach running

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a computer simulation of the taught model and how the bolus drug delivery is relatively simple to implement. Howson et al. at the abstract and Fig. 1 teach a drug delivery unit, that is customizable for a particular patient to assure proper drug delivery along which comprises a computer and a display.

Kern et al. do not explicitly teach a drug display monitor, which displays the present and future probability of effectiveness.

Minto et al. at the abstract teach a review of clinical applications of population pharmacodynamic and pharmacokinetic modeling. Furthermore, Minto et al. teach at page 330, that software packages that implement the instantly taught models with easy to use graphical user interfaces are being developed. Minto et al. at page 330, conclusions section, teach that the taught type of modeling has many clinical applications, which can be a powerful tool for exploring the factors influencing interpatient variability in the dose-response relationship and that modeling can also be applied to developing optimal dosing strategies.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have implemented the software packages along with easy to use graphical user interfaces envisioned by Minto et al. to run the combination of pharmacokinetic and pharmacodynamic models as taught by Kern et al. and display in real time the model outputs on a monitor to ensure safe drug deliver as taught by Howson et al. This is because one of ordinary skill in the art could have applied the use of easy to use software programs with user friendly graphical user interfaces to run the known pharmacokinetic and pharmacodynamic models to display the model outputs

simultaneously for safer drug delivery and it would have yielded predictable results and resulted in an improved method.

Kern et al. at page 207 teach using the taught invention with an infusion pump as in claim 7.

Kern et al. at page 202 teach running a computer simulation of the taught model, which reads on claims 8-10.

Kern et al. at the abstract and page 204, simulating anesthetic agents and at page 202 wherein the simulation simulates Pancuronium, a neuromuscular blocking agent, which reads on claim 11.

Kern et al. at Fig. 5 teach a graph that can be used to represent drug concentration that will have a desired effect as in claims 19 and 36.

Kern et al. teach at Fig. 5 simulating the effect of a neuromuscular drug. Kern et al. at the abstract and page 204 teach wherein the agent can be an anesthetic, muscle relaxant etc. Furthermore, Anesthetic agents, which would be administered for purposes of anesthesia represent a probability of effectiveness on a subject at: causing the subject to lose consciousness and eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain. Anesthesia, as evidenced by google, is either local, general, or regional and the desired effects of anesthetic agents at the local, general, or regional level is evidenced by the definitions of general, local, and regional anesthesia; such as “General anesthesia puts the patient to sleep,” (i.e. loss of consciousness) “local anesthesia numbs a specific body part. Regional anesthesia, such as spinal anesthesia and epidural anesthesia, numbs the nerves that conduct sensation to a

circumscribed body area." Therefore, a system that comprises a display monitor configured to depict drug concentrations, which represent a probability of effectiveness, where the drugs are anesthetic agents, represents drug concentrations with a probability of effectiveness where that effectiveness includes a subject at: causing the subject to lose consciousness and eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain, which reads on claims 14-15, 20-21, 31-32, 35 and 37-38.

Kern et al. teach at 20 wherein the simulation running the pharmacokinetic and pharmacodynamic models use multiple parameters, which includes dosing and doing period and a delivery scheme as in claims 22-24. Minto et al. teach at page 321 using population pharmacokinetic and pharmacodynamic modeling to develop optimal initial dosing guidelines wherein interpatient variability exists. Minto et al. further teach at page 321 that the population models seek to obtain improved estimates of the pharmacokinetic and pharmacodynamic parameters in light of observed responses in the population, which reasonably and broadly reads on a probability of effectiveness being depicted as a percent likelihood based on results from a population as in claims 16-18 and 29-30.

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Claims 25-28 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kern et al. (1997) in view of Minto et al. (1998) as applied to claims 6-11 and 14 above and further in view of Howson et al (US P/N 5,088,981).

Kern et al. and Minto et al. do not explicitly teach a data decoder.

Howson et al ('981) discloses a drug display monitor (28) comprising a data decoder (20) receiving data from the data stream device (50); a dosage calculator (32) receiving decoded data from the data decoder; a drug modeler (26) and normalizer (24) receiving calculated data from the data decoder; a storage device (16), receiving drug and dosage data from the drug modeler and normalizer; and a display generator (28), wherein the display generator produces a display of more than one drug dosages, drug name, past, present and predicted drug site concentration and effect site concentration in three-dimensional form and a system for data representation comprising a processor (16), computing drug models, producing an internal representation of drug display data and decoding a data stream; a memory unit in communication with the processor; a graphics adapter (24c) in communication with the processor and a display monitor in communication with the graphics adapter, see figures 1 and 2 and col. 13, 14 and 15, which reads on claims 12 and 13 and 35.

Howson et al. at figures 1 and 2 and col. 13, 14 and 15 teach a display monitor, which reads on a display of the instantly claimed methods as discussed above, further reads on being configured to depict past probabilities of effectiveness as in claim 14, 15 and 39-50.

Furthermore, the examiner views a processor, which is already capable and configured to displaying drug model data will inherently be configured for such functionality as causing the graphics adapter and the display monitor to graphically depict a percent likelihood that the at least one drug has a desired effect. In particular, Howson et al. does teach a processor that inherently causes the graphics adapter to

display real time drug effectiveness data streams. Therefore, it is inherent that the processor is configured and capable of performing such functionality as recited in the claims.

With respect to claims 25-28 and 33-34: Howson et al. at figures 1 and 2 and col. 13, 14 and 15 teach a display monitor, which reads on a display of the instantly claimed methods as discussed above and a processor already configured to processing drug model data. However, Howson et al. does not explicitly teach a processor configured for such functionality as causing the graphics adapter and the display monitor to graphically depict a percent likelihood that the at least one drug has a desired effect.

However, the examiner views a processor, which is already capable and configured to displaying drug model data will inherently be configured such functionality as causing the graphics adapter and the display monitor to graphically depict a percent likelihood that the at least one drug has a desired effect. In particular, Howson et al. does teach a processor that inherently causes the graphics adapter to display real time drug effectiveness data streams. Therefore, it is inherent that the processor is configured and capable of performing such functionality as recited in the claims.

Double Patenting-Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 6-11, 15, and 19 of copending Application No. 10/269422 in view of Johnson et al (US P/N 5,522,798). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Howson et al fails to explicitly disclose that the drug monitor is configured to depict past, predicted and real-time probabilities of effectiveness. Johnson et al discloses a similar device, which does graphically depict past, predicted and real-time drug concentrations (col. 17. line 44 and col. 12 line 9), which read on past, predicted and real-time probabilities of effectiveness. Johnson et al., at col. 7, discloses how these concentrations are calculated based on drug data that may be uploaded, patient history data, or PK model data, all of which are used to calculate and deliver a particular drug concentration. The data that the calculations are dependent are based on correlations between concentrations and effectiveness. A patient's history data helps establish a record of what concentrations had what effects on a patient and enable a prediction of a concentration and an expected probability of effectiveness to be calculated based on this data, drug data, or PK model data. In other words, a display of a past, predicted, or real-time concentration of a drug, is a display of a past, predicted, or real-time probability of effectiveness since the calculations are based on known data that correlates concentrations, time, and effectiveness. Therefore, a drug monitor that graphically depicts past, predicted, and real-time drug concentrations are necessarily configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject. Moreover, Johnson et al teaches that the display monitor is configured to depict a percent likelihood that the at least one drug has a desired effect based on results from a predefined population that is at least ninety-five

percent of the population and wherein a plurality o inputs includes the height and weight of the subject (see col. 15 line 60).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Howson et al by incorporating the graphical drug concentration display of the type taught by Johnson et al in order to give the physician information in evaluating the need for changes in the desired drug concentration set point for a more accurate probability of effectiveness(col. 17 line 49).

This is a provisional obviousness-type double patenting rejection.

Response to arguments:

Applicant argues that obviousness-type double patenting rejection be held in abeyance until all other issues have been resolved.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin/
Primary Examiner, Art Unit 1631